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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,106	02/11/2004	Eric Bornstein	093991-0020	2676

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EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,106	BORNSTEIN, ERIC	
	Examiner	Art Unit	
	david shay	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 8 and 18, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,8,34,35,37,46-48 and 50-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,8,34,35,37,46-48 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *August 18, 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

With the instant response applicant has filed a Declaration by Dr. Eric Bornstein (hereinafter "Declarant") in support of the patentability of the instant claims. The examiner will now analyze the Declaration. But first the examiner will summarize the statements made in the Declaration. Initially Declarant notes that he is the inventor of the claimed subject matter. In paragraph 1 Declarant notes that he is the Chief Scientific officer and founder of Nomir Technologies from 2003 to the present. In paragraph 2, Declarant discusses his educational Background. In paragraph 3, Declarant notes his extensive experience with infectious microorganisms and the use of lasers to treat them. In paragraph 4, Declarant discusses his consulting experience, and the development of dosimetry parameters for various clinical studies treating various microbial pathogens. In paragraph 5, Declarant asserts that he exemplifies "the hypothetical person that is 'one having ordinary skill in the art'" and points to over a dozen articles and presentations on the use of lasers authored by Declarant. In paragraph 6, Declarant asserts to have read and understood the rejection applied under 102(e) based on Goodman, and notes that Goodman no longer anticipates the claimed ranges, which have been limited by the redaction of the modifier "about". In paragraph 7, Declarant asserts to have read and understood the rejection applied under 102(e) based on Tromberg et al, and notes that Tromberg et al no longer anticipates the claimed ranges, which have been limited by the redaction of the modifier "about". In paragraph 8, Declarant asserts to have read and understood the rejection applied under 102(e) based on Merilainen, and notes that Merilainen no longer anticipates the claimed ranges, which have been limited by the redaction of the modifier "about". In paragraph 9, Declarant notes that none of the references teach the specific wavelength ranges of 865-875 nm and 925-935 nm, nor do they recognize the cytotoxic effect of the wavelength ranges, without

which recognition, the references cannot serve as the basis for a rejection under section 103 of the statute. In paragraph 10, Declarant notes that none of the cited references teaches the newly added limitation that "the power delivered by the first and second wavelengths is the majority of the total power of near infrared radiation output by the device." In paragraph 11, Declarant asserts to have read and understood the rejection applied under 103 based on Goodman. In paragraph 12, Declarant asserts to have read and understood the rejection applied under 103 based on Tromberg et al. In paragraph 13, Declarant asserts to have read and understood the rejection applied under 103 based on Merilainen. In paragraph 14, Declarant states that "the power outputs given in my invention are not directly equivalent to those disclosed by Grable" asserting that to compare the values they must be adjusted for pulse length and asserts that after such adjustment there is a difference of 8 orders of magnitude between the power of Grable and that of the instant claims. In paragraph 15, Declarant then states that in his opinion, one of ordinary skill in the art in the medical laser field would not combine Grable with the other references. In paragraph 16, Declarant calculates the peak pulse power for a laser pulse such as taught by Grable, noting that the disclosed peak power of Grable is consistent with the calculation. In paragraph 17, Declarant states that the peak power disclosed by Grable "is a tremendous amount of energy if it is applied to a single point" referring to a figure mapping out the effects of various power densities for various exposure times. In paragraph 18, Declarant asserts that it would not be obvious to combine the teachings of Grable with those of Goodman, since the only reason the tissue is not damaged is due to the scanning optics creating a fan shaped beam, noting further that in a hand scanned embodiment, Grable notes that the power must be reduced below that of the mechanically scanned embodiment. In paragraph 19, Declarant asserts

that it would not be obvious to combine the teachings of Grable with those of Tromberg et al, since the only reason the tissue is not damaged is due to the scanning optics creating a fan shaped beam, noting further that in a hand scanned embodiment, Grable notes that the power must be reduced below that of the mechanically scanned embodiment. In paragraph 20, Declarant asserts that it would not be obvious to combine the teachings of Grable with those of Merilainen, since the only reason the tissue is not damaged is due to the scanning optics creating a fan shaped beam, noting further that in a hand scanned embodiment, Grable notes that the power must be reduced below that of the mechanically scanned embodiment. In paragraph 20, Declarant states that one of ordinary skill in the art would recognize that the devices described in the applied references are designed for long exposure times, and that such a skilled artisan would recognize the undesirability of using high levels of energy per pulse in long exposure time devices. In paragraph 22, Declarant states the Neumann paper (of record) is considered by those of ordinary skill in the art to be a landmark study, and those of ordinary skill in the art, such as the authors of the applied references would avoid the wavelength ranges of Neumann, and would not have applied these wavelengths at the power levels taught by Grable. In paragraph 23, Declarant reiterates the statements regarding the use of the newly claimed frequency ranges and the newly added power limitations already set forth in paragraphs 9 and 10. In paragraph 24, Declarant notes that none of the applied references relate to tissue sparing infection control procedures. In paragraph 25, Declarant notes the importance of new antimicrobial treatments, asserting a long felt need for new antimicrobial treatments. In paragraph 26, Declarant states that the instant invention fulfills the long felt need. In paragraph 27, Declarant states that invention offers treatment of microbial infection without the toxic systemic effects of currently employed drug

treatments. In paragraph 28, Declarant states that the instant invention also does not cause local tissue damage as do current photo-treatments for infections, which employ ablation. In paragraph 29, Declarant states that the NOVEON™ system reduces infections and avoids detrimental effects to healthy tissue, and that this is confirmed by clinical trials and peer review of the data. In paragraph 30, Declarant states that the NOVEON™ system is currently under review by the FDA, and while not yet approved, physicians have requested that these devices be reserved for them in anticipation of FDA approval, and asserts that this establishes commercial success of the device.

With regard to paragraphs 1-13 the examiner agrees with Declarant, in view of the newly amended claim language, with the exception of the following. The examiner cannot agree with Decla5rant's assertion that he exemplifies "the hypothetical person that is 'one having ordinary skill in the art'". As an inventor, Declarant has established himself as one of *extraordinary* skill in the art. Indeed, if the examiner were to conclude that Declarant were the hypothetical person that is 'one having ordinary skill in the art', then anything that Declarant had conceived would have been obvious to the hypothetical person that is 'one having ordinary skill in the art', and would by definition not be patentable, and this is clearly not the case here. With regard to paragraphs 14, the examiner is at a loss to determine how Declarant has reached the conclusion concerning the difference in power between the device of Grable and the instant device. As a first point it is noted that the statements in a Declaration are only convincing as they are drawn to the claimed invention. The specification and claims are completely devoid of any reference to either pulse repetition rate or pulse width, and the claimed invention is silent with regard to any power which may be associated therewith. It is also noted that the originally filed disclosure

seems to treat pulsed and continuous wave application of the light as equivalent. Thus no "unit energy/pulse" can fairly be derived from the originally filed disclosure, and thus any assertions as to the difference between this value for the instant device as compared to that of Grable are not convincing. With regard to paragraph 15, Declarant's opinion is noted, however, the fact that Grable recognizes as specifically states that the power of the beam has to be modified so as to image while not damaging tissue clearly shows that this knowledge is within the scope of one of ordinary skill in the art. With regard to paragraph 16, while Declarant's calculations are noted, the fact remains that Grable discloses (and claims, in one of the parent cases, which matured into U. S. Patent No. 6,195,580) an imaging system, specifically for diagnosis. As one of ordinary skill in the art is well aware, a diagnostic system which alters the character of the tissue in the course of the diagnosis cannot be relied upon to provide data from which to formulate any sort of treatment, since the state of the tissue recorded has been changed by the fact that it was examined. Further, one of ordinary skill in the art would also be well aware that the use of diagnostic systems which damage healthy tissues is at best ill advised. With regard to paragraph 17, the examiner must respectfully note that Declarant has misconstrued the nature of the Figure referred to therein. The ordinate of the graph is clearly labeled "Power density" and as such the power must have an area of exposure associated with it. However, there is no area associated with the power calculation related to the pulses of Grable. In fact, the Grable publication discusses no exposure area with relation to the laser beam for either the mechanically scanned or the hand scanned embodiment. Thus the location of the 92KW mark on the ordinate is meaningless, as we do not know if Grable was projecting this power into a spot of one square micron, one squar centimeter, or one square meter. With regard to paragraph 18, Declarant's

disagreement with the combination is noted, however, as set forth above with regard to the conclusions drawn in paragraph 16, one of ordinary skill in the art would readily understand, that a diagnostic procedure need be conducted in a way as to not damage the healthy tissue. With regard to paragraph 19, Declarant's disagreement with the combination is noted, however, as set forth above with regard to the conclusions drawn in paragraph 16, one of ordinary skill in the art would readily understand, that a diagnostic procedure need be conducted in a way as to not damage the healthy tissue. With regard to paragraph 20, Declarant's disagreement with the combination is noted, however, as set forth above with regard to the conclusions drawn in paragraph 16, one of ordinary skill in the art would readily understand, that a diagnostic procedure need be conducted in a way as to not damage the healthy tissue. With regard to paragraph 21, Declarant's disagreement with the combination is noted, however, as set forth above with regard to the conclusions drawn in paragraph 16, one of ordinary skill in the art would readily understand, that a diagnostic procedure need be conducted in a way as to not damage the healthy tissue. With regard to paragraph 22, Declarant's conclusion is noted, however, there is no evidence that the wavelength chosen by the author of the art applied to the claims was chosen in light of the article by Neumann. With regard to paragraphs 23-30, the examiner notes that statements made therein are set forth as facts by Declarant.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 8, 34, 35, 46-48, and 50-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on "wherein the power of the delivered infrared radiation in the first and second wavelength ranges is the majority of the total power of near infrared radiation delivered to the infected site".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 52 are indefinite because it is unclear what the difference in scope of these claims is.

Claims 2, 34, 37, 46, and 50, are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hall et al.

See Table I. T

Claim 8, 35, 47, 48, 51, and 52 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al in combination with Grable. Hall et al teach a device as claimed, but does not disclose a particular power. Grable teaches that powers in applicant's disclosed range are appropriate for diagnosing tissue, the manual scanning embodiment constituting a control to adjust the power density. It would have been obvious to the artisan of ordinary skill to employ

the laser power of Grable in the device of Hall et al, since this would produce the power necessary for determining the desired tissue parameters, and in any case it would have been obvious to the artisan of ordinary skill to use a digit clip, since this is standard for determining blood oxygenation, official notice of which is hereby taken, and to multiplex or alternate the wavelengths, since this is not critical; is well within the scope of one having ordinary skill in the art; and provides no unexpected result, thus producing a device such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 8, 34, 35, 37, 46-48, and 50-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent Application No. 11/825,550. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass

the instant application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 8, 34, 35, 37, 46-48, and 50-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent Application No. 11/841,348. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 8, 34, 35, 37, 46-48, and 50-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of

U.S. Patent Application No. 11/981,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 8, 34, 35, 37, 46-48, and 50-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent Application No. 11/997,665. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or

narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 8, 34, 35, 37, 46-48, and 50-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent Application No. 12/019,336. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed March 11, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 2, 8, 34, 35, 37, and 45-48 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769